



**NC State Health Director's Statewide Standing Order  
for Administering Pfizer-BioNTech Covid-19 Bivalent Vaccine as the primary series and booster in Children 6  
months through 4 Years  
April 21, 2023**

**Purpose:** To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and to administer Pfizer-BioNTech (herein-after Pfizer vaccines) to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA [Emergency Use Authorization](#).

**Policy:** This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina [Session Law 2022-74, Sec. 9G.7.\(a\)-\(e\)](#) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.

Note: On April 18, 2023, the FDA rescinded the EUA of all mRNA monovalent COVID-19 vaccine products. This decision was based on data reflecting the overall improved effectiveness of the bivalent vaccines vs. monovalent vaccines and the fact that the most prominently circulating SARS- CoV2 strains are of Omicron BA.4/BA.5 lineage. This action also simplifies the vaccination schedule for most individuals.

On April 28, 2023, the FDA authorized the following uses of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 6 months through 4 years of age with certain types of immunocompromise who have previously received three 0.2 mL doses (Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent):

- a fourth dose administered at least 1 month following the most recent dose;
- additional doses that may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

COVID-19 Vaccination	
<b>Condition/ Situation:</b>	<p><b>ALERT:</b> Pfizer monovalent COVID-19 vaccine is no longer authorized in this age group. All children <b>6-months through age 4</b> are eligible for Pfizer bivalent vaccine.</p> <p>Patients present requesting vaccination will receive, with appropriate written consent from an authorized caregiver:</p> <ul style="list-style-type: none"><li>➤ <b><u>Unvaccinated children:</u></b> Administer 3 doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent over the course of 11 weeks. The first two doses are administered three weeks apart. The third dose is administered at least 8 weeks after the second dose. After completion of the 3 doses, this child is considered fully vaccinated. NO booster dose is required.</li><li>➤ <b><u>Children who have received 1 dose of Pfizer-BioNTech monovalent COVID-19 Vaccine:</u></b> Administer 2 bivalent doses: the first dose shall be given 3 weeks after the first monovalent vaccine; the second dose shall be given at least 8 weeks after the first bivalent dose. Children completing this schedule are NOT eligible for a booster vaccine.</li><li>➤ <b><u>Children who have received 2 doses of Pfizer-BioNTech monovalent COVID-19 Vaccine:</u></b> Administer a single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent at least 8 weeks after the last monovalent Pfizer-BioNTech COVID 19 vaccine.</li></ul>



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- **Children who have received 3 doses of monovalent vaccine:** Administer a single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent at least 8 weeks after the last monovalent Pfizer-BioNTech COVID 19 vaccine.
- **Immunocompromised individuals 6 months through 4 years of age:** For children who have received three 0.2 mL doses ((Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent), administer a single additional dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent at least 1 month following the most recent dose.

If the parent requests additional doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent for their immunocompromised child, refer to their healthcare provider for an individual medical order.

**Individuals 6 months of age 4 years of age not previously vaccinated with a COVID-19 vaccine**

Age	Pfizer-BioNTech COVID19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule of Pfizer-BioNTech COVID-19 Vaccine Bivalent
<b><u>6m-4y<sup>1</sup></u></b>	<b><u>Maroon</u></b>	3 doses, 0.2 mL each The first 2 doses are administered 3 weeks apart. The third dose is administered at least 8 weeks after the second dose.

<sup>1</sup> Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.



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<b>Individuals 6 months through 4 years of age previously vaccinated with the monovalent Pfizer-BioNTech COVID-19 Vaccine<sup>2</sup></b>			
<b>Age</b>	<b>Number of Previous Doses of Pfizer-BioNTech COVID-19 Vaccine Monovalent</b>	<b>Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color</b>	<b>Dosing Regimen, Dose and Schedule of Pfizer-BioNTech COVID-19 Vaccine Bivalent</b>
6m-4y	1 previous dose	Maroon	Administer 2 doses <sup>3</sup> at 0.2 mL each. The first dose is given three weeks after the monovalent Pfizer-BioNTech COVID-19 vaccine and the second dose is at least 8 weeks later.
6m-4y	2 previous doses	Maroon	Administer a single dose, 0.2 mL at least 8 weeks after receipt of second dose of Pfizer-BioNTech COVID-19 Vaccine
6m-4y	3 previous doses	Maroon	Administer a single dose, 0.2 mL at least 8 weeks after receipt of third dose of Pfizer-BioNTech COVID-19 Vaccine
<sup>2</sup> The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States. <sup>3</sup> Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive 2 doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.			



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Assessment Criteria	
Assessment Criteria	<p>Patients <b>6 months through 4 years</b> of age shall be vaccinated with Pfizer BioNTech COVID-19 Vaccine, Bivalent based on:</p> <ol style="list-style-type: none"><li>1. The conditions/situations of this order (see above).</li><li>2. The patient is presenting for first dose or subsequent dose/s of Pfizer and there is no history of previous COVID-19 vaccination using another vaccine brand.</li><li>3. The patient is presenting for a dose of Pfizer and the minimum interval between doses has been met (for further guidance see <a href="#">CDC Clinical Considerations COVID-19 vaccination schedule</a>)</li><li>4. Availability of maroon cap under 5 vaccine, bivalent formulation.</li></ol>
Plan of Care	
Actions	<p><b>Patient Education and Data Collection</b></p> <p>Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include:</p> <ol style="list-style-type: none"><li>1. Review <a href="#">CDC Pre-Vaccination Checklist for COVID-19 Vaccine</a>.</li><li>2. <a href="#">Fact Sheet for Recipients and Caregivers About Pfizer-BioNTech COVID-19 Vaccine for 6 Months through 4 Years of Age</a>. Patient's authorized caregiver should consult primary care or other health care provider if they have questions regarding which COVID-19 vaccine they should receive. Refer to <a href="#">Interim Clinical Considerations</a> for latest vaccine information.</li></ol>
	<p><b>Pfizer COVID-19 Vaccine 6 months through 4 years:</b></p> <p><b>Administration Procedures</b></p> <ol style="list-style-type: none"><li>1. Review <a href="#">Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States</a>.</li><li>2. Pfizer COVID-19 vaccine for pediatric patients 6 months through 4 years of age is supplied in a <b>MAROON CAP</b> formulation. No other formulation should be used in this population. The vaccinator shall be familiar with procedures for preparation, storage &amp; handling of the Pfizer formulation they are using.<ol style="list-style-type: none"><li>a. Review the <a href="#">Fact Sheet for Healthcare Providers Administering Pfizer Vaccine for 6 Months Through 4 Years</a> (MAROON CAP ONLY)</li></ol></li><li>3. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine.</li><li>4. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to</li></ol>



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vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.

5. Review *Special Circumstances*, *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine. More information is available at this site - CDC [COVID-19 Vaccines for Special Populations](#).
6. Following the current [CDC Pre-Vaccination Checklist for COVID-19 Vaccines](#), instruct patients accordingly or consult with overseeing provider.
  - a. The pre-vaccination checklist shall be followed with the following exception: COVID-19 vaccination should **not** be deferred in patients who received monoclonal antibody treatment or convalescent plasma.
7. When vaccinating a minor with **Pfizer COVID-19 vaccine**, consent must be obtained from the patient's authorized caregiver prior to administration per conditions of this order, agency policy and in accordance with [NC General Statute 90-21.13](#) and [Minor Consent Law](#) and [Session Law 2021-110. \(Section 9, a1\)](#)
8. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per [CDC guidelines for COVID-19 vaccinations](#) to protect against the transmission of COVID-19.

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**Vaccine Product & Preparation:**

1. **Vaccine product:** Ensure the appropriate Pfizer formulation, based on age is selected.
  - a. The Pfizer bivalent formulation for ages 6 months through 4 years has a **MAROON CAP** and label: "Bivalent (Original and Omicron BA.4/BA.5). This vaccine must be diluted prior to use. Discard 12 hours after the first puncture.
2. **Preparation:** Prepare vaccine, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling prepared vaccine. When using the **MAROON CAP** formulation, refer to Pfizer COVID-19 Vaccine Fact Sheet for Health Care Providers Dose Preparation for 6 months through 4 years formulation (MAROON CAP) Once vial is punctured it must be discarded after 12 hours.
3. **Dosing:**
  - a. Administer 0.2 mL (3 µg) Pfizer COVID- bivalent vaccine to patients 6 months through 4 years of age based on dose sequence **Diluent is required.**



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	<b>Pfizer-BioNTech COVID-19 Vaccine, Bivalent Multiple Dose Vaccine Vial Cap and Label Color</b>	Amount of Sterile 0.9% Sodium Chloride Injection to Use as Diluent
	Maroon caps and labels with maroon borders	2.2 mL
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	<b>Children, 3-5 years</b>	16-25 mm	*5/8 inch-1 inch	Deltoid muscle
		25-32 mm	1-1.25 inch	Anterolateral thigh
<p>b. <b>Needle Gauge:</b> Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their reported weight. A patient's authorized caregiver may self-report the child's weight for needle selection purposes. *If a 5/8-inch needle is used, skin must be stretched tightly (<b>do not bunch subcutaneous tissue</b>).</p> <p>11. <b>Multiple vaccinations:</b> If multiple vaccines are administered at a single visit, administer each injection in a different injection site following guidance in the <a href="#">CDC Interim Clinical Considerations - COVID-19 vaccine and coadministration with other vaccines</a>.</p> <p>12. <b>Bleeding Risk:</b> Patients with blood disorders or who are on blood thinners: administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes.</p> <p>13. <b>Documentation:</b></p> <ol style="list-style-type: none"> <li>Patient or caregiver attestation to severe or moderate immunocompromise should be done within the notes section in CVMS or comparable section of an EHR or other documenting systems..</li> <li><b>CVMS/NCIR:</b> Document vaccine record in CVMS or NCIR <b>within 24 hours</b> after vaccine administration per system guidelines found at: <a href="https://immunize.nc.gov/providers/covid-19training.htm">https://immunize.nc.gov/providers/covid-19training.htm</a>. If vaccine is documented in the EHR within 24 hours, providers have <b>no more than 72 hours</b> from administration to also enter data in CVMS or NCIR. Determining whether to document in CVMS versus NCIR should occur according to site protocol; it is not necessary to document in both systems.</li> <li><b>Electronic Medical Record:</b> If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.</li> <li>Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacture, lot number, date of vaccination, name/location of vaccinator and clinic site.</li> <li>Counsel when and how patient needs to schedule return appointment for second, third, or booster dose of COVID-19 vaccine, if applicable.</li> </ol>				



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	<p><b>Pfizer COVID-19 Vaccination Observation and Follow-Up</b></p> <ol style="list-style-type: none"> <li>1. <b>Post-vaccination Observation:</b> Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the <a href="#">Centers for Disease Control and Prevention guidelines</a> for the following time periods: <ol style="list-style-type: none"> <li>a. <b>30 minutes:</b> <ul style="list-style-type: none"> <li>• Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine</li> <li>• Persons with a history of anaphylaxis due to any cause</li> <li>• People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson who receive a mRNA vaccine-Pfizer or Moderna/SPIKEVAX) should be observed for 30 minutes following vaccination.</li> <li>• Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy</li> </ul> </li> <li>b. <b>15 minutes:</b> All other persons</li> </ol> </li> <li>2. <b>Anaphylaxis Management:</b> Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to <a href="#">severe allergic reactions and anaphylaxis</a>.</li> <li>3. <b>Syncope:</b> Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.</li> </ol>
<p><b>Special Circumstances</b></p>	<p><b>People who received COVID-19 vaccination outside the United States:</b> The recommendations for people vaccinated outside of the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Refer to Interim Clinical Considerations, Appendix A (<a href="#">People who received COVID-19 vaccine outside the United States</a>) and take action/ consult with medical provider as directed.</p> <p><b>Participants in clinical trials within or outside the United States</b> U.S. trial participants, along with non-U.S.-based participants in the same trial, who received all the recommended primary series doses of a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy are considered <a href="#">up to date</a> with their COVID-19 vaccines when they have received a <b>bivalent mRNA booster dose</b>. At this time, only the Medicago COVID-19 Vaccine in people ages 18 years and older meet these criteria.</p>






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	<p><u><a href="#">Appendix B. People who received COVID-19 vaccine as part of a clinical trial</a></u></p> <ol style="list-style-type: none"> <li>1. If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider. Clinical trial participants who did not receive all the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.</li> </ol>
<b>Follow-up</b>	<p>Adverse events that occur in a recipient following COVID-19 vaccination should be reported to <u><a href="#">VAERS</a></u>. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:</p> <ol style="list-style-type: none"> <li>1. Vaccine administration errors</li> <li>2. Serious adverse events</li> <li>3. Cases of Multisystem Inflammatory Syndrome</li> <li>4. Cases of COVID-19 that result in hospitalization or death.</li> </ol> <p>Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at <u><a href="https://vaers.hhs.gov">https://vaers.hhs.gov</a></u> or by calling 1-800-822-7967.</p>
<b>Precautions for Use of this Order</b>	<ol style="list-style-type: none"> <li>1. Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction.</li> <li>2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – COMIRNATY/Pfizer or Moderna/SPIKEVAX) because of potential cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions.</li> <li>3. Patient self-reported moderate to severe acute illness.</li> <li>4. Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination.</li> <li>5. Persons with a history of myocarditis or pericarditis.</li> <li>6. Persons with a history of MIS-C or MIS-A.</li> </ol>



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April 21, 2023**

<b>Contraindications for Use of this Order</b>	<p>Do not administer the COVID-19 Vaccine to individuals with a history of:</p> <ul style="list-style-type: none"><li>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine</li><li>• Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.</li></ul> <p>See additional guidance: <a href="#">Interim Clinical Considerations, Appendix E: Triage of people with history of allergies or allergic reactions</a></p>
<b>Criteria or Circumstances for Notifying Medical Provider</b>	<ol style="list-style-type: none"><li>1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.</li><li>2. Patient reports a precaution for the vaccine.</li><li>3. COVID-19 vaccine history cannot be determined or is not available.</li><li>4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US.</li><li>5. Patients vaccinated with active COVID-19 vaccine as part of a clinical trial.</li><li>6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred.</li><li>7. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order.</li></ol> <p>Note: Healthcare providers or health departments in the United States can request a consultation from <a href="#">CISA COVID vax</a> for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or <a href="#">Advisory Committee on Immunization Practices (ACIP)</a> guidelines.</p>

Approved by:   
Elizabeth Cuervo Tilson  
NPI: 1760540421

Date Signed: 5-8-23

This standing order is effective immediately and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina [Session Law 2022-74, Sec. 9G.7.\(a\)-\(e\)](#), or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively “vaccinators”) to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.